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Nobushige Doisaki

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EXAMINER

WINSTON, RANDALL O

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**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Application Number: 10/535,413
Filing Date: November 17, 2005
Appellant(s): DOISAKI ET AL.

Sadao Kinashi
For Appellant

EXAMINER'S ANSWER

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This is in response to the appeal brief filed July 7, 2008 appealing from the Advisory action mailed 06/19/2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

6,235,331	Kataoka et al.	5-2001
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6,242,479	Wechter	6-2001
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Granata WO 02/058793 08-2002

Chavali et al. DWPI Abstract 2002-040630 and/or US 20010031275 10-2001

Maguire et al. DWPI Abstract 1995-054394 02-1995

Tallarida, Ronald J. "Drug Synergism and Dose-Effect Data Analysis"

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(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 1-3 and 5-20 are rejected under 35 USC 103(a) as being unpatentable over Kataoka et al. (US 6235331) or and Granata (WO02/058793)in view of Chavali et al. (US 20010031275, DWPI Abstract), Maguire et al. (DWPI Abstract, 1995-054394), Chen et al. (US 20020156051, DWPI Abstract) and Wechter (US 6242479).

A composition comprising an organic substance having a double bond (i.e. eicosapentaenoic acid ethyl ester (EPA) or docosahexaenoic acid ethyl ester(DHA)) which contains an antioxidant comprising an anti-oxidative sesame component (i.e. the elected species of a sesamol) which is purified form sesame or synthesized and either ascorbic acid or ascorbyl fatty acid ester and further comprising a tocopherol.

Both Kataoka or Granata teach that eicosapentaenoic acid ethyl ester (EPA) or docosahexaenoic acid ethyl ester (DHA)treats cardiovascular disorders (see, e.g. in Kataoka the entire document including column 1 lines 24-39 and in Granata the entire document including abstract). [please note that Katoka teaches that eicosapentaenoic acid ethyl ester (EPA) or docosahexaenoic acid ethyl ester(DHA) is obtained from fish oil. Moreover, the claimed eicosapentaenoic acid ethyl ester (EPA) or claimed docosahexaenoic acid ethyl ester (DHA) would also intrinsically be of an organic substance with a double bound]. Kataoka or Granata, however, does not expressly teach the other claimed active ingredients such as sesamol, ascorbic acid or ascorbyl fatty acid ester and tocopherol are contained within its composition to treat cardiovascular disorders.

Chavali beneficially teaches that elected species of sesamol treats cardiovascular disorders (see, e.g. DWPI abstract). [please note that elected species of the pure sesamol intrinsically has the characterized in claim 7]

Maguire beneficially teaches that ascorbyl palmitate treats cardiovascular disorders (see, e.g. DWPI abstract).

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Chen beneficially teaches that ascorbic acid treats cardiovascular disorders. (see, e.g. DWPI abstract).

Wechter beneficially teaches that tocopherol treats cardiovascular disorders. (see, e.g. entire document including abstract).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify either Kataoka or Granata composition's teachings to include the other claimed active ingredients of sesamol, ascorbic acid or ascorbyl fatty acid ester (i.e. ascorbyl palmitate) and tocopherol as taught by Chavali, Maguire, Chen and Wechter within Kataoka or Granata composition's teachings because the above combined teachings would create the claimed invention's composition to treat cardiovascular disorders. Moreover, as discussed in MPEP Section 2114.06, "it is prima facie obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to used for the same purpose." The adjustments of other conventional working conditions (i.e. determining suitable amounts/ranges of each claimed active ingredient within the claimed composition, the substitution of one claimed form of the composition to be administered for the another and the fish oil form), is deemed a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention was prima facie obvious to one of ordinary skill in the art at the time the invention was made, especially in the absence of evidence to the contrary.

Please note that the patentability of a product does not depend upon the method of production. If the product in a product-by-process claim is the same as or obvious from a product of the prior art, then the claim is unpatentable even though the prior art product was made by a different process” (see, e.g. MPEP 2113).

(10) Response to Argument

In regards to the 35 USC 103(a) rejection based on the combination of Kataoka et al. (US 6235331) or and Granata (WO02/058793) in view of Chavali et al. (US 20010031275, DWPI Abstract), Maguire et al. (DWPI Abstract, 1995-054394), Chen et al. (US 20020156051, DWPI Abstract) and Wechter (US 6242479), the appellant argues the cited references do not teach or suggest the combination of ingredients because the anti-oxidative sesame component and ascorbic acid or an ascorbyl fatty acid ester are not added to modify the composition of Kataoka or Granata, or to form a third composition to be used for the same purpose. Instead, these (i.e. anti-oxidative sesame component and ascorbic acid or an ascorbyl fatty acid ester) are added to form a third composition which has dramatically improved oxidative stability.

The examiner disagrees with the appellant's argument because the appellant is broadly claiming any/all amounts of each claimed active ingredient [please note, appellant is claiming a composition comprising the active ingredients eicosapentaenoic acid ethyl ester (EPA) or docosahexaenoic acid ethyl ester (DHA) in combination with sesamol and ascorbic acid and/or ascorbyl fatty acid ester and/or tocopherol] within the claimed composition. As discussed in MPEP Section 2114.06, “it is *prima facie* obvious

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to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose (i.e. each claimed active ingredient is taught in prior art to be useful in treating cardiovascular disorders), in order to form a third composition to be used for the same purpose.” Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify either of the compositions taught by Kataoka or Granata by including the other claimed active ingredients of sesamol, ascorbic acid or ascorbyl fatty acid ester (i.e. ascorbyl palmitate) and tocopherol as taught by Chavali, Maguire, Chen and Wechter therein because the above combined teachings would create a composition as claimed - for the intended use of treating cardiovascular disorders, as described in the rejection above.

Secondly, appellant argues the *prima facie* case obviousness has been effectively rebutted by factual evidence as shown in Figures 1, 5, and 14 to demonstrate the significance of the synergistic effect of combining each claimed active ingredient.

The examiner disagrees with the appellant's argument because the amounts of each active ingredient which demonstrate the unexpected synergism (as shown in Figures 1, 5, and 14), are not present in the claims. The synergistic amounts shown in Figures 1, 5, and 14 only vary from 1-2% of the sesame component and 0.01% -0.5% ascorbyl palmitate. The claims are not limited to any particular amounts of active ingredients and thus the claims encompass non-synergistic amounts of the active ingredients. In order for the appellant's argument of synergism to be persuasive to overcome the *prima facie* case of obviousness as set forth above, the claimed composition needs to claim the amounts of the active ingredients sufficient to obtain the

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unexpected results due to synergism. Therefore, since the claimed composition is not limited to the active ingredients being present in amounts shown to be synergistic and thus demonstrate unexpected results, the assertion of unexpected results does not overcome the prima facie case of obviousness as set forth in the rejection above. As discussed in MPEP Section 2114.06, "it is *prima facie* obvious to combine two or more compositions each of which is taught by the prior art to be useful for the same purpose (in the instant case, each claimed active ingredient is taught in to prior art to be useful in treating cardiovascular disorders), in order to form a third composition to used for the same purpose."

Lastly, the appellant argues that unexpected results are not limited to specific amounts of each claimed active ingredient because it is natural for a person of ordinary skill in the art to conclude similar results will be obtained for the amounts or ranges other than those shown in the embodiments.

The examiner disagrees for the same reasons as above. Additionally, even though it is agreed that there may be some other concentrations or ranges of concentrations that are synergistic and thus have unexpected results, it is not agreed that all concentrations of active ingredients encompassed by the claimed compositions would be synergistic and thus overcome the prima facie case of obviousness established in the rejection above. For example, Ronald J. Tallarida in his book named "*Drug Synergism and Dose-Effect Data Analysis*" on pages 8-10 provides a statistical analysis of an isobologram for the hypnotic effect of a combination of ethyl alcohol and chloral hydrate. In his figures, Tallarida discloses an isobologram showing line of

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additive and curves for combinations that are synergistic and sub-additive. Tallarida states that the figures show that some of the data points appear to be well off the line of additivity, while others are close to the line and have error bars that intersect it.

Therefore, Tallarida concludes that some combinations are synergistic whereas others are simply additive. Tallarida implies that synergism is not only a property of the drug pair but also depends on the relative amounts in the combination tested. This reference shows the general principle that unexpected synergism between components of a composition is present in only a range of proportions of the components in an unpredictable fashion.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Randall O Winston

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October 22, 2008

Conferees:

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